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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,316	02/04/2002	Yaguang Liu		3984

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EXAMINER
FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1654	6

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/062,316	Liu
Examiner	**Art Unit**
Michele Flood	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 19, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-13, 17, and 44-53* is/are pending in the application.

4a) Of the above, claim(s) *1-13, 17, and 47-53* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *44-46* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on June 19, 2003. Acknowledgment is made of Applicant's cancellation of Claims 26-43, and newly submitted Claims 44-53.

Election/Restriction

Newly submitted claims 47-53 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: In Paper No. 3, Applicant originally elected without traverse the invention of Group IV, Claims 14-16 and 18-25, directed to a botanical drug comprising a polysaccharide of Dang Gui containing soybean-liposomes (DGL) and LX- containing soybean-liposomes (LXL) which is used for treatment and prevention of malignant pleural effusion and cancer, and enhancement of immune function, whereas newly submitted Claims 47-53 are directed to two additional inventions. For example, the invention of Claim 47 is directed to a drug comprising DGL used for enhancement of immune function and inhibiting oncogenes and cancer incidence and the invention of Claims 48-53 is directed to a drug comprising LXL used for treatment and prevention of cancer and malignant pleural effusion.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the

merits. Accordingly, claims 47-53 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 44-46 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's arguments have been fully considered but the rejection remains for the reasons set forth in the previous Office action and for the reasons set forth below.

As set forth in the previous Office action, the specification lacks adequate written description guidance as to what plant ingredients comprise the instantly claimed drug. Applicant only refers to the plant ingredients as "Dang Gui containing soybean-liposomes (DGL)" and "LX-containing soybean-liposomes (LXL)", i.e., "Lan Xiang Xi containing soybean-liposomes". Further, based on a computer-assisted literature search, the overall state of the art does not appear to adequately teach any or all of such plant ingredients or preparations. For instance, a search on the term "Dang Gui" identifies "Dang Gui" as *Radix Angelica sinensis* or Chinese

angelica root. However, a search on the term "Lan Xiang Xi" found no results. Accordingly, it is not known by the instant teachings what is the Latin genus-species names of the plants Applicant intends to direct the subject matter of the instantly claimed invention. Yet still, it is not known by the instant teachings if the leaves, stems, flowers, berries, roots, bark, and/or other part(s) of each of the two disclosed plant ingredients are being used to form the claimed therapeutic composition. The only apparent guidance provided by the instant specification is on page 3, lines 15-29, which briefly discloses that the starting material of the plant ingredients are in the form of powder and that they are subjected to process steps of extraction. For example, on page 3, lines 28-29, under "Example 2 LX extraction", Applicant discloses "One kg of plant powder was extracted 5 L of water at room temperature for 12 hours. The powder of plant named Dryobalanops aromatica Gaerin or Wen E Shu was recovered by filtration." However, it is unclear as to what are the constituents of the "One kg of plant powder" that was extracted with 5 L of water. It is also uncertain as to what is the relation of "the powder of plant named Dryobalanops aromatica Gaerin or Wen E Shu" that was recovered by the process of filtration to "Lan Xiang Xi".

On page 3 of Applicant's "Remarks", lines 5-7, of Paper No. 5 (dated March 13, 2003) Applicant states "Lan Xiang Xi is a **pure ingredient** extract from plant, which has Latin genus-species name: *Curcuma aromatica Salisb.*" On page 3, lines 9-10, Applicant adds, "Further on, 'Lan Xiang Xi is not a name of plant. It is one ingredient extracted from *Curcuma aromatica Salisb.*" Applicant further states on page 3 of the "Remarks", lines 20-21, "One kg of plant powder" means one kg powder of *Curcuma aromatica Salisb* or one kg powder of root tuber of

Curcuma aromatica Salisb. However, nowhere in the disclosure of the as-filed specification does Applicant disclose that the claim-designated ingredient, Lan Xiang Xi, is obtained from *Curcuma aromatica Salisb*. Instead, it appears from Applicant's disclosure that Lan Xiang Xi is somehow related to "a plant named Dryobalanops aromatica Gaerin or Wen E Shu", as disclosed on page 3, line 29 of the instant specification. At present, it is unclear from Applicant's "Remarks" and disclosure whether the above mentioned Wen E Shu is one and the same as *Curcuma aromatica Salisb* or whether it represents a different plant name. Thus, Applicant's remarks are inconsistent with the showing of the disclosure of the specification. Furthermore, while Applicant's "Remarks" identifies Lan Xiang Xi as an ingredient obtained from *Curcuma aromatica Salisb* having specified chemical and physical properties, Applicant has yet to identify the Latin genus-species name of Dang Gui. (However, the purposes of examination of the claims for prosecution on the merits, the Office regards the claim-designated Dang Gui as *Angelica sinensis* since Applicant did not argue that the result of the Office's search on the term is other than *Angelica sinensis*. Finally, the Office notes that while the claims are directed to a drug comprising a polysaccharide of Dang Gui containing soybean-liposomes and Lan Xiang Xi containing soybean liposomes, the specification discloses only a polysaccharide of Dang Gui mixed with soybean-liposomes and Lan Xiang Xi mixed with soybean liposomes. As set forth in the previous Office action, the specification fails to teach what is the Latin genus-species name of the plant ingredients comprising the claimed therapeutic composition or what part or parts of these plants are used in the making of the powders which are used in extraction processes for the making of

the claimed therapeutic composition. Moreover, it is well known in the art that different parts of plants contain highly variable, distinct active ingredients therein, making the use of any and all parts of such plants highly unpredictable in terms of successfully preparing a composition having the therapeutic effects instantly disclosed and claimed. Applicant is reminded that although the use of common names or traditional/ethnopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical noted in this application.

Based on the lack of guidance provided by the instant specification and the overall state of the art, as well as the highly unpredictability in determining which plants or which plant part(s) contain particular active ingredients therein, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to prepare a safe botanical drug having Based on the lack of guidance provided by the instant specification and the overall state of the art, as well as the highly unpredictability in determining which plants or which plant part(s) contain particular active ingredients therein, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to prepare a drug having the disclosed/claimed therapeutic effects from the two recited ingredients of "Dang Gui containing soybean-liposomes (DGL)" and "LX-containing soybean-liposomes (LXL)".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

With regard to Claim 44, line 2, the word which should be placed after "(LXL)" to place the claim in proper grammatical form.

Claim 45 recites the limitation "wherein the amount" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 46 is rendered indefinite by the phrase "wherein said liposomes contained hydrogenated phosphatidly choline (PC), phosphatidyl glycerol (PG), and phophatidyl serine (PS), which purified from soybean" because the limitations of a claim should be drafted to include a positive statement. For instance, Applicant may overcome the rejection by replacing "contained" with the word contains and adding is after "which" to place the claim in proper grammatical form.

With regard to Claim 46, line 3, the word is should be placed after "which" to place the claim in proper grammatical form.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MCF

July 28, 2003

CHRISTOPHER R. TATE
PRIMARY EXAMINER